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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,242	07/15/2003	Ricky Ulrich	003/267/SAP	8917

7590 09/24/2007
ATTN: MCMR-JA (Ms. Elizabeth Arwine- PATENT ATTY)
U. S. Army Medical Research and Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/620,242	Applicant(s) ULRICH ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 49-54, 59, 60 and 64-67.
 Claim(s) withdrawn from consideration: 1-48, 55-58 and 61-63.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed September 14, 2007 has been received and entered. Claims 1-67 remain pending in the instant application, of which claims 1-48, 55-58, and 61-63 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

1. The objection of claims 53-54 and 58-60 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim remains withdrawn in view of Applicants amendment.

Applicants indicate that these claims have been amended, however this appears to be a reference to an action done in the previous response. This objection was withdrawn in the previous response and remains withdrawn.

Claim Rejections - 35 USC § 112

2. The rejection of claims 64-67 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

It is noted that Applicants have requested that this rejection be held in abeyance until the claims are allowed. However, until the deposit is perfected, this rejection is maintained for reasons of record.

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The specification lacks complete deposit information for the deposit of GB8:bpml3, it is not clear that host cells possessing the identical properties of GB8:bpml3 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a host cell is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed cell, this method will not necessarily reproduce host cells which are chemically and structurally identical to those claimed. Undue experimentation would be required to screen all of the possible species to obtain the claimed host cells.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the GB8:bpml3 host cells a suitable deposit for patent purposes, evidence of public availability of the GB8:bpml3 host cells or evidence of the reproducibility without undue experimentation is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological

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material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if the test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 49-54, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by DeShazer et al is maintained.

Applicants are asserting that Bmal3 is a synthase enzyme which functions in the synthesis of n-acyl-homserine lactones. Applicants assert that Deshazer do not discuss Bmal3, nor an enzyme similar to Bmal3. Applicants further assert that since "fragments thereof" are not recited in the claims, it cannot be read as part of the claims.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that Bmal3 is a synthase enzyme which functions in the synthesis of n-acyl-homserine lactones. This statement is agreed upon. However, the claims simply do not limit the structure (e.g., SEQ ID NO:). Furthermore, Applicants specification clearly contemplates sequences which comprise "substantially different from those described... or fragments thereof." (Page 14). Yes, the nucleic acid encoding the protein described by DeShazer et al is "substantially different" from Bmal3 of Applicants invention (SEQ ID NO: 2). However, Applicants claims do not recite SEQ ID NO: 2, and as set forth above encompass substantially different fragments.

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Combined with the transitional phrase of "comprising" which allows for changes upstream or downstream of the fragment, the disclosure of DeShazer et al fully anticipates the instantly claimed invention. Finally, Applicants assert that the claims do not recited "fragments thereof" and therefore cannot be read into the claims. However, Applicants specification (page 14) defines Bmal3 to include fragments. Accordingly, when given the broadest reasonable interpretation, the claims clearly encompass fragments of the described nucleic acid encoding the protein.

The claims are directed to a mutant *B. mallei* strain with reduced virulence wherein said strain is altered in expression or function of Bmal3.

DeShazer et al (Microbial Pathogenesis (Vol. 30, pp 253-269, May 2001) disclose of *B. mallei* strains with reduced virulence having disrupted *yggB*, *yafJ*, *manC*, *wcbB*, *wcbF*, *wcbL*, *wcbM*, *wcbP*, *wcbQ*, and *wcbR* genes. (See abstract, Figure 2 and Materials and Methods section).

It is noted that Applicants specification specifically sets forth that nucleic acid molecules of the invention "comprise a sequence substantially different from those described, but which due to the degeneracy of the genetic code, still encode the protein **or fragments thereof.**" (Specification pages 14 & 15).

In view that DeShazer et al disclose of *B. mallei* strains with reduced virulence having disrupted genes, which genes inherently share "fragments" (which can be as small as a single codon) in common with the Bmal3 gene referenced in the claims, the disclosure of DeShazer et al is deemed to anticipate the claimed invention.


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For reasons of record as well as the reasons set forth above, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Navarro
Primary Examiner
September 20, 2007